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From John J. Gagel

Re U.S. Serial No. 09/185,732

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Message PLEASE DELIVER TO EXAMINER RUSSEL.

(A) 1/1 VASCath v. Mahurkar 19 USPQ2d 1111 112 F1

tions that did not follow ineluctably [i.e., inevitably] from the diagrams." *Id.* at 524, 17 USPQ2d at 1357. As an example, the court stated (presumably with respect to independent claims 1 and 7 of the '329 patent) that

> the utility patents claim a return lumen that is "substantially greater than one-half but substantially less than a full diameter" after it makes the transition from semi-circular to circular cross-section, and the drawings of serial '081 fall in this range. But until the utility application was filed, nothing established that they had to—for that matter that the utility patent would claim anything other than the *precise* ratio in the diagrams....

Id. at 523, 17 USPQ2d at 1357. Mahurkar argues that one of ordinary skill in this art, looking at the '081 drawings, would be able to derive the claimed range.

The declaration of Dr. Stephen Ash, submitted by Mahurkar, is directed to these concerns. Dr. Ash, a physician specializing in nephrology (the study of the kidney and its diseases) and chairman of a corporation that develops and manufactures biomedical devices including catheters, explains why one of skill in the art of catheter design and manufacture, studying the drawings of the '081 application in early 1982, would have understood from them that the return lumen must have a diameter within the range recited by independent claims 1 and 7 of the '329 patent. Dr. Ash explains in detail that a return (longer) lumen of diameter less than half that of the two lumens combined would produce too great a pressure increase, while a return lumen of diameter equal or larger than that of the two lumens combined would result in too great a pressure drop.[7] "Ordinary experience with the flow of blood in catheters would lead directly away from any such arrangement," Ash states.

Although the district court found this reasoning "logical," it noted that later patents issued to Mahurkar disclose diameter ratios closer to 1.0 (U.S.Patent No. 4,584,968) and exactly 0.5 (U.S.Des.Patent No. 272,651). If these other ratios were desirable, the district court queried, "how does serial '081 necessarily exclude the[m]?" 745 F.Supp. at 523, 17 USPQ2d at 1357.

[6, 7] The district court erred in taking Mahurkar's other patents into account. Mahurkar's *later* patenting of inventions involving different range limitations is irrelevant to the issue at hand. Application sufficiency under § 112, first paragraph, must be judged as of the filing date. *United States Steel Corp. v. Phillips Petroleum Co.*, 865 F.2d 1247, 1251, 9 USPQ2d 1461, 1464 (Fed.Cir.1989).

[8] The court further erred in applying a legal standard that essentially required the drawings of the '081 design application to *necessarily exclude* all diameters other than those within the claimed range. We question whether any drawing could ever do so. At least with respect to independent claims 1 and 7 of the '329 patent and claims depending therefrom, the proper test is whether the drawings conveyed with reasonable clarity to those of ordinary skill that Mahurkar had in fact invented the catheter recited in those claims, having (among several other limitations) a return lumen diameter substantially less than 1.0 but substantially greater than 0.5 times the diameter of the combined lumens. Consideration of what the drawings conveyed to persons of ordinary skill is essential. *See Ralston Purina*, 772 F.2d at 1575, 227 USPQ at 179 (ranges found in applicant's claims need not correspond *exactly* to those disclosed in parent application; issue is whether one skilled in the art could derive the claimed ranges from parent's disclosure).

7. Higher pressure drops are associated with smaller cross-sectional areas for fluid flow. Mahurkar's opening brief to this court states that by applying well-known principles of fluid mechanics (i.e., the work of Poiseuille and Hagen), it can be calculated that the diameter of the circular (return) lumen would have to be in the range of 0.66 times the diameter of the two lumens combined in order to achieve proper blood flow at equal pressure drop. The 0.66 ratio falls within the noted claim limitation.

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the touch, open celled foamy mass made up of interlaced interconnected strips of varying width and thickness which may appear fibrous or skin-like. The majority of the cells formed by this *plexilamellar* protein structure are.... [Emphasis added.]

[13] The third finding is similar to the first, and fails for a similar reason. The Dutch publication discloses the use of a standard extruder which, at the time, came equipped with the structure specified in the Flier patent. The publication is therefore not deficient as to this element of Flier's claims.

As a result of our disposition of this issue, only those claims entitled to the effective filing date, July 10, 1964, of the parent application remain in issue. The trial court held and Ralston does not contest, that claims 1–9, 14, 29–31, and 33–52 were entitled only to the effective filing date of the 1966 application. Thus, we hold these claims to be invalid for having been described in a printed publication before the invention thereof by the applicant for patent. 35 U.S.C. § 102(a).

Description Requirement

[14–16] The trial court held that claims 10–13, 15–28, and 32 of Flier are entitled to the effective filing date of the 1964 parent application because the parent application complies with the written description requirement of 35 U.S.C. § 112, first paragraph, which is incorporated in 35 U.S.C. § 120. Whether the description requirement is met is a question of fact reviewable under the clearly erroneous standard. *In re Wilder*, 736 F.2d 1516, 1520, 222 USPQ 369, 372 (Fed.Cir.1984), *cert. denied*, —— U.S. ——, 105 S.Ct. 1173, 84 L.Ed.2d 323 (1985). The trial court properly recognized that the test for sufficiency of support in a parent application is whether the disclosure of the application relied upon "reasonably conveys to the artisan that the inventor had possession at that time of the later claimed subject matter." *In re Kaslow*, 707 F.2d 1366, 1375, 217 USPQ 1089, 1096 (Fed.Cir.1983). Precisely how close the original description must come to comply with the description requirement of 35 U.S.C. § 112 must be determined on a case-by-case basis. *In re Wilder*, 736 F.2d 1516, 1520, 222 USPQ 369, 372 (Fed.Cir.1984).

Far-Mar-Co cites several range cases to support its argument that ranges found in the applicant's claim language must correspond exactly to ranges disclosed in the parent. These cases are not in point. The facts in these cases precluded a determination that one skilled in the art could derive the claim limitations from the parent, due to a number of different factors, e.g., the unpredictable nature of the art, *In re Sichert*, 566 F.2d 1154, 196 USPQ 209 (CCPA 1977); failure to distinguish one process from another, *In re MacLean*, 454 F.2d 756, 172 USPQ 494 (CCPA 1972); the addition of a critical limitation, *In re Bluser*, 556 F.2d 534, 194 USPQ 122 (CCPA 1977); failure to define a critical term, *In re Lukach*, 442 F.2d 967, 169 USPQ 795 (CCPA 1971); and use of a list that did not contain the claimed substance. *In re Ahlbrecht*, 435 F.2d 908, 168 USPQ 293 (CCPA 1971). In addition, a predecessor to this court has held "that a claim may be broader than the specific embodiment disclosed in a specification is in itself of no moment." *In re Rasmussen*, 650 F.2d 1212, 1215, 211 USPQ 323, 326 (CCPA 1981). Far-Mar-Co argues that the claims remaining in issue contain new matter at least with respect to the protein content of the starting material, total and added moisture, temperature ranges, and the situs of fiber formation. Far-Mar-Co contends that although the 1964 parent application would enable one skilled in the art to practice the invention claimed, it does not meet the description requirement under 35 U.S.C. § 112.

With respect to protein content, Far-Mar-Co argues that the claim language "protein content of at least about that of solvent extracted soybean meal" is not supported by the language of the parent application, which speaks of "soybean meal having a low fat and high protein content." The parent application also states that "[s]uch 50% protein soybean meal is well known and frequently is a by-product of the process of oil extraction from soybeans. Such meal is preferably solvent extracted to de-

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crease the fat content thereof to the range mentioned above." Further, "[s]oybean meal having a protein content of approximately 50% is the preferred meal component for use in the present invention. When, however, the meal has a protein content of substantially less than 50%, it may be mixed with a high protein component which will increase the protein content of the combination to the preferred 50%."

[17] The trial court found that the parent disclosure does support the claim language, based on the 1964 disclosure and on consideration of the knowledge possessed by those skilled in the art of extrusion of both farinaceous and proteinaceous vegetable materials in 1964. The trial court found that soybean meal of 44%, 50%, 70%, and 90% protein were standard, available commodities in 1964. The trial court also found that the parent, which disclosed a "high protein content" and a preferred lower level but no upper limit, and indicated that protein content could be adjusted, reasonably conveyed adjustment of the protein content of soybean meal to levels above 50%. Having considered Far-Mar-Co's arguments, we conclude that the court did not clearly err in determining that the parent's disclosure adequately supports the protein content of the claims in issue.

[18] With respect to temperature, Far-Mar-Co argues that the claim limitation "in excess of 212° F" and "substantially above 212° F" are not supported by the parent application. The trial court found that experts from both parties were in substantial agreement that the parent application sets the critical lower limit for temperature at 212° F and supports this limit in the patent claims. The trial court considered evidence of what the skilled artisan would appreciate about the sources of heat in the process, both steam heat and the pressure brought to bear on the mixture, as well as the limitations of the equipment disclosed. The trial court also noted that Far-Mar-Co's expert agreed that the claim language calling for the temperature "being increased substantially" found support in the parent application. On the basis of this record, it was not clear error for the court to find sufficient disclosure in the parent application for the above-mentioned limitations.

[19] Far-Mar-Co argues that the trial court clearly erred in finding support in the parent for the moisture content limitations. The trial court considered (1) evidence that the purpose of moisture in the mix was to make the material flow through the extruder; (2) the physical characteristics of mixtures with varying levels of water; (3) the type of test and degree of accuracy in testing for moisture level; and (4) the approximate amount of moisture known by those skilled in the art to be contained in soybean meal. Based on this evidence and the formulations disclosed in the parent application, the court allowed both parties to calculate approximate upper and lower moisture limits supportable by the parent application. It found inadequate descriptive support in the parent application for the moisture limitations of "at least about 20%" and of those claims calling for a total moisture content "between about 20% and 40% by weight," and the parties do not contest these findings. The court found adequate support for moisture levels of "at least about 25% by weight," "at least 25% by weight," and "in the range of 20–30% of the resulting mixture." The trial court noted that claims simply calling for sufficient water to permit the resulting mixture to be passed through an extruder or calling for approximately 25% of the mixture were not challenged. The trial court's rationale for striking down the claims with endpoints of 20% and 40% was that these limits could not be justified solely by the so-called ball test for moisture content. Those claims would convey new information to one skilled in the art. The open-ended claims, however, would be limited by what a person skilled in the art would understand to be workable. After careful consideration of Far-Mar-Co's arguments, we conclude that the court did not clearly err in determining that the parent's disclosure adequately supported the water ranges of "at least about 25% by weight," and "at least 25% by weight." The court, however, did clearly err in finding support in the parent for the limitation: "in the range of

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flexible cylindrical member of resilient material rolled outwardly upon itself to form a single roll ...." (Emphasis added). We held that, although the "flexible" and "single roll" limitations made the reissue claim narrower than both the canceled and issued claims, it did not escape the recapture rule because these limitations did not "materially narrow the claim[ ]." Id. at 996-97, 27 USPQ2d at 1525-26.

Similarly, in Ball, the issued claim recited "a plurality of feedlines" and a "substantially cylindrical conductor." 729 F.2d at 1432-33, 221 USPQ at 291-92. The canceled claim recited "feed means includ[ing] at least one conductive lead," and a "substantially cylindrical conductor." The prosecution history showed that the patentee added the "plurality of feedlines" limitation in an effort to overcome prior art, but the cylindrical configuration limitation was neither added in an effort to overcome a prior art rejection, nor argued to distinguish the claims from a reference. Id. The reissue claim included limitations not present in the canceled claims that related to the feed means element, but allowed for multiple feedlines. On balance, the claim was narrower than the canceled claim with respect to the feed means aspect. The reissue claim also deleted the cylindrical configuration limitation, which made the claim broader with respect to the configuration of the conductor. Id. at 1437, 729 F.2d 1429, 221 USPQ at 295. We allowed the reissue claim because the patentee was not attempting to recapture surrendered subject matter. Id. at 1438, 729 F.2d 1429, 221 USPQ at 296.

[10] In both Mentor and Ball, the relevance of the prior art rejection to the aspects narrowed in the reissue claim was an important factor in our analysis. From the results and reasoning of those cases, the following principles flow: (1) if the reissue claim is as broad as or broader than the canceled or amended claim in all aspects, the recapture rule bars the claim; (2) if it is narrower in all aspects, the recapture rule does not apply, but other rejections are possible; (3) if the reissue claim is broader in some aspects, but narrower in others, then: (a) if the reissue claim is as broad as or broader in an aspect germane to a prior art rejection, but narrower in another aspect completely unrelated to the rejection, the recapture rule bars the claim; (b) if the reissue claim is narrower in an aspect germane to prior art rejection, and broader in an aspect unrelated to the rejection, the recapture rule does not bar the claim, but other rejections are possible. Mentor is an example of (3)(a); Ball is an example of (3)(b).

[11] In our case, reissue claim 49 is both broader and narrower in areas relevant to the prior art rejections. Comparing reissue claim 49 with claim 42 before the May 1988 and June 1987, amendments (see the tables at Appendices A and B), we see that claim 49 is narrower in one area, namely, the brightness is "at least 59 ISO in the final pulp." This narrowing relates to a prior art rejection because, during the prosecution of the '179 patent, Clement added this brightness limitation in an effort to overcome Burns. Our comparison also reveals that reissue claim 49 is broader in that it eliminates the room temperature and specific energy limitations of step (a), and the temperature, specific energy, and pH values of steps (c) and (d). This broadening directly relates to several prior art rejections because, in an effort to overcome Ortner, Clement added to step (a) the limitation that it is carried out "at room temperature," and applies "specific *1471 mechanical energy lower than 50 KW.H/Ton to form a pumpable slurry...." He argued, moreover, that the latter limitation overcame Burns despite the examiner's contention to the contrary. Clement also added to steps (c) and (d) the temperature and specific energy values in an effort to overcome Ortner, and the "strong" alkaline conditions "having a pH of at least 9" limitation in an effort to overcome Burns. Clement admitted, furthermore, that he added these "very specific process parameters ... in order to distinguish over the prior art." Claim 49 omits each of these limitations.

On balance, reissue claim 49 is broader than it is narrower in a manner directly pertinent to the subject matter that Clement

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Recapture

The new reissue claims are method of treatment claims. For example, claim 18 is a method of treating tissue to prevent or control air or fluid leaks:

> A method of treating tissue to prevent or control air or fluid leaks comprising:
>
> providing a composition to tissue, said composition including an albumin protein and a crosslinking agent, said crosslinking agent having a polyoxyethylene chain portion and an activated leaving group which allows the crosslinking agent to react with said protein; and
>
> curing said composition on the tissue to bond said composition to the tissue and to provide a substantive cured matrix.

The Barrows et al. patent has method of treatment claims. These are claims 9-12, all of which are independent claims. Claim 12, for example, is a method of preventing or controlling blood or other fluid leaks:

> An *in vivo* method to seal tissue comprising the step of topically applying and bonding the adhesive mixture of claim 1 to tissue to prevent or control blood or other fluid leaks.

20. An *in vivo* method to prevent post-surgical adhesions comprising the step of applying and curing the adhesive mixture of claim 1 to tissue surrounding a surgical site.

21. An *in vivo* method to seal tissue comprising the step of applying and bonding the adhesive mixture of claim 1 to tissue to prevent or control blood or other fluid leaks.

Claims

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1. An adhesive composition consisting essentially of a i) first aqueous mixture of protein in about a 0.01-0.25 molar buffer at a pH in the range of about 8.0-11.0 and a ii) second aqueous mixture of a crosslinking agent of the formula

G-LM-PEG-LM-G

wherein -PEG- is a diradical fragment represented by the formula

$$-O-(CH_2-CH_2-O-)_a-$$

where a is an integer from 20-300;

wherein -LM- is a diradical fragment selected from the group consisting of a carbonate diradical of the formula, -C(O)- , a monoester diradical of the formula, $-(CH_2)_bC(O)-$ where b is an integer from 1-5, a diester diradical of the formula, $-C(O)-(CH_2)_c-C(O)-$ where c is an integer from 2-10 and where the aliphatic portion of the diradical may be saturated or unsaturated, a dicarbonate diradical of the formula $-C(O)-O-(CH_2)_d-O-C(O)-$ where d is an integer from 2-10, or an oligomeric diradical represented by the formulas -R-C(O)-, $-R-C(O)-(CH_2)_c-C(O)-$, or $-R-C(O)-O-(CH_2)_d-O-C(O)-$ wherein c is an integer from 2-10, d is an integer from 2-10, and R is a polymer or copolymer having 1-10 monomeric fragments selected from the group consisting of lactide, glycolide, trimethylene carbonate, caprolactone and p-dioxanone; and

wherein -G is a leaving group selected from the group consisting of succinimidyl, maleimidyl, phthalimidyl, imidazolyl, nitrophenyl or cresyl.

2. The adhesive mixture of claim 1 wherein the protein in the first mixture is serum albumin.

3. The adhesive mixture of claim 2 wherein the protein in the first mixture is about 20-60 wt/vol% serum albumin.

4. The adhesive mixture of claim 2 wherein the protein in the first mixture is about 35-45 wt/vol% serum albumin.

5. The adhesive composition of claim 2 wherein the serum albumin is human serum albumin.

produce a nontoxic adsorbable adhesive sealant composition which may be used to bond and/or seal tissues *in vivo*." The mentioned motivation is opined to reside in the teachings or suggestions of the for other cited references.

Applicants respectfully submit that the invention of pending claims 18-34 would not be obvious to one of ordinary skill in the art. Importantly, there is nothing in the references, alone or combined, which suggests that the recited combination of serum albumin protein and crosslinking agent would function as an *in vivo* tissue adhesive or sealant nor is there any motivation to combine the references in the manner suggested. Specifically, the Abuchowski et al. and D'Urso references report immunogenically modified materials but do teach or suggest adhesive or sealant properties. Rubinstein and WO 90/13540 report modified enzymes or hydrolysis-resistant proteins but again do not teach or suggest adhesive or sealant properties. The TISSEEL kit brochure reports a fibrin sealant which is a physiological adhesive that relies on the interaction of fibrin and thrombin to form an enzymatically-mediated coagulated mixture but also does not teach or suggest adhesive or sealant properties of the present composition. These listed references do not report any teaching or suggestion of the present invention.

Applicants note that the only report of adhesive properties using a gelatin/polyhydric alcohol system is provided in Potaczek. This reference however, does not teach or suggest the present adhesive composition or the use of the present composition as a tissue adhesive or sealant to one of ordinary skill in the art. Simply put, the compositions of Potaczek could not be used to bond or seal tissue *in vivo* because these reported adhesive compositions are formed by the removal of water at high temperatures.

In sum, Applicants submit that the references do not teach or suggest the present invention to one of ordinary skill in the art and that the motivation to combine the references in order to teach or suggest the present invention has not been demonstrated. Applicants request that the Examiner withdraw the rejection under 35 U.S.C. §103.

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Further, Applicants direct the Examiner's attention to the data listed in Table 4. These data demonstrate that the adhesive composition of the present invention provides an unexpected substantive matrix as measured by burst strength. For example, the present compositions provide much higher burst strengths compared to either a crosslinked bovine fibrinogen composition or fibrin glue.

In view of the foregoing amendment and remarks, Applicants submit that pending claims 18-34 are in condition for allowance and request that the Examiner pass the application to issuance.

Respectfully submitted,

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Date

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